FEB 2 4 2014

DALTON INSTRUMENT CORP
16300 Addison Road, Suite 120
Addison, TX 75001
Ph: 469-522-1200 Fax: 469-522-1202

Lift Chair

LC-106 510(K) APPLICATION

K131909

Section 5

510(k) Summary

(Per 21 CFR 807.92)

1. Submitter's Name and Contact Information:

Mrs. Mei Lein
Dalton Instrument Corp.
16300 Addison Road, Suite 120
Addison, TX 75001
Email: daltonint@gmail.com
Phone: (469) 522-1200
Fax: (469) 522-1202

Summary Preparation Date: 20 February 2014

2. Device Identification:

Proprietary Name:	Dalton Lift Chair, Model LC-106
Generic Name:	Electric Positioning Chair
Classification:	Class II
Product Code:	INO
Regulation Number:	21 CFR 890.3110
Review Panel Code:	Physical Medicine

3. Predicate Device

The proposed 'Dalton Lift Chair, LC-106' is substantially equivalent to the Lift Chair Model C5 manufactured by Pride Mobility Products Corp., previously cleared under K070950.

4. Description of Device

The Dalton Lift Chair, Model LC-106 is intended to provide lift assistance for persons who have difficulty rising from a seated position to a standing position. It uses standard AC power from an electrical outlet. The device is mainly made of a welded steel frame, upholstery fabric and foam. The chair is assembled to welded steel lifting frame mechanism having a 24V DC motor/actuator powered by AC power from an electrical outlet. A hand-held control device engages the actuator to position the chair to recline, sitting, or standing position.

5. Indications for Use

The intended use of the Dalton Lift Chair, Model LC-106 is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.

6. Summary of Similar Technological Characteristics

Dalton Instrument Corp. 'Dalton Lift Chair, LC-106' and predicate device 'Lift Chair C5' (K070950) are intended to provide lift assistance for persons who have difficulty rising from a seated position to a standing position. They have the same intended use and indications for use. Their operating principle and technological characteristics are also comparable, as outlined in the following table:

Characteristics / Features	**Subject Device**	**Predicate Device K070950**
	Dalton Lift Chair, Model LC-106 (Dalton Instrument Corp.)	**Lift Chair, Model C5 (Pride Mobility Products Corp.)**
Classification	Class II	Class II
Product Code Regulation	INO 21 CFR 890.3110	INO 21 CFR 890.3110
Indications for Use	The intended use of the Dalton Lift Chair, Model LC-106 is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.	The Intended Use of the Pride Mobility C5 Lift Chair is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.
Design / Construction		
Basic Platform	Welded Steel Lifting Frame	Welded Steel Lifting Frame
Drive Mechanism / Actuator	Delta Drive DC 24V (manufactured by Okin Refined Electric Technology Co. Ltd.)	Delta Drive DC 24V (manufactured by Okin Refined Electric Technology Co. Ltd.)
Command Input	Hand-held Control device to operate the various functions of the lift chair, such as positioning to recline, sitting or standing position	Hand-held Control device to operate the various functions of the lift chair, such as positioning to recline, sitting or standing position
Upholstery Fabric (Chair Cover)	Made of Microsuede / Microfiber (Polyester material)	Made of Polyester material

Characteristics / Features	Subject Device	Predicate Device K070950
	Dalton Lift Chair, Model LC-106 (Dalton Instrument Corp.)	**Lift Chair, Model C5 (Pride Mobility Products Corp.)**
Chair Cushion	Made of Foam (Polyurethane material)	Made of Foam (Polyurethane material)
General and Technical Specifications		
• **Maximum Duty cycle (Mode of operation)**	2 min ON / 18 min OFF	2 min ON / 18 min OFF
• **Power Requirements**	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz
• **Operating Temperature**	10°C (50°F) to 40°C (104°F)	10°C (50°F) to 40°C (104°F)
• **Weight Capacity**	235 lbs (107 kg)	325 lbs (147 kg)
• **Weight of Lift Chair**	133 lbs	133 lbs
• **Maximum Tilt Angle**	45 Degree	Not Specified
• **Seat Height**	19" (483 mm)	18" (457 mm)
• **Seat Width**	20" (508 mm)	19" (483 mm)
• **Seat Depth**	20" (508 mm)	20" (508 mm)
• **Overall Width**	33" (838 mm)	32.75" (832 mm)
• **Overall Height**	43" (1092 mm)	Not specified
• **Arm Height**	25.6" (650 mm)	Not specified
• **Overall Reclined Depth**	69" (1753 mm)	Not specified
• **Overall Upright Depth**	34.6" (879 mm)	Not specified

7. Non-Clinical Testing

The proposed Dalton Lift Chair LC-106 was evaluated per IEC 60601-1:1988/A1:1991/A2:1995 for basic safety. The Electromagnetic Compatibility of the device was evaluated per IEC 60601-1-2. All tests were completed successfully.

The Dalton Lift Chair LC-106 was tested per standard 'California Technical Bulletin No. 117: Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture'.

The Upholstery Fabric (Chair Cover) of the Dalton Lift Chair LC-106 that may come in contact with patients is biocompatible. The material was evaluated for Cytotoxicity per ISO 10993-5 and for Skin Irritation and Dermal Sensitization per ISO 10993-10.

8. Clinical Testing

The submission does not rely on any clinical data; therefore no clinical testing was performed.

9. Conclusion:

Based on design, technological characteristics, performance specifications and non-clinical bench testing information provided in the submission; the proposed Dalton Lift Chair LC-106 is substantially equivalent to the predicate device, and does not raise any new concerns of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 24, 2014

Dalton Instrument Corporation
c/o Ms. Mei Lein
16300 Addison Road, Suite 120
Addison, TX 75001

Re: K131909
Trade/Device Name: Dalton Lift Chair, Model LC-106
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: January 10, 2014
Received: January 14, 2014

Dear Ms. Lein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131909

Device Name
Dalton Lift Chair, Model LC-106

Indications for Use *(Describe)*
The intended use of the Dalton Lift Chair, Model LC-106 is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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